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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,487	09/30/2003	Toshihiko Matsuo	MATSUO3	1529

7590

07/06/2005

BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
Washington, DC 20001-5303

EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,487	MATSUO ET AL.	
	Examiner	Art Unit	
	Robert Shiao	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 05/12, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/05/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
JAPAN 285784/2002 with a filing date 09/30, 2002.
2. Amendment including addition of claims 7-12 in the amendment filed on May 12, 2005 is acknowledged. Claims 1-12 are pending in the application. No new matter is found.

Responses to Election/Restriction

3. Applicant's election with traverse of claims 7-12 having compounds of Group I (i.e., compounds of formulae 14-17), in part, in the reply filed on May 12, 2005, is acknowledged. The traversal is on the grounds that examination of claimed invention should be conducted on the basis of such a new use of the organic dye. This is found not persuasive, and the reasons are given, *infra*.

Status of the Claims

4. Claims 1-12 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 7-12, in part, drawn to method of use of organic dye, wherein the organic dye represent formula 14, 15, 16, or 17 thereof, classified in classes 546/548, numerous subclasses.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn

compounds/methods of use contain varying functional groups (i.e., heteroaryl or heterocycloalkyl of the formulae 1-17) which differ from those of the elected invention such as oxazole, quinoline, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 548 subclass 215(+) (oxazole), class 546 subclass 134(+) (quinoline), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 7-12, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 7-12, in part, not embraced in above elected subject matter, and claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter “evoking a receptor potential in response to photostimulation in the optic nerve” and “an organic dye compound” without limitation, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, see claim 7, lines 1-3.

6. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant methods treating dyschromatopsia, does not reasonably provide enablement for a method of evoking a receptor potential other than dyschromatopsia or claimed compounds other than formulae 1-17, i.e., detachment of retina or a compound having morpholine moiety. The specification does not enable any person skilled in the art to which it pertains, with which it is most nearly connected, to use the invention commensurate in scope with these claims, see claim 7 or 8, lines 1-3.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the Disclosure.

See below:

1) Nature of the invention

The claims are drawn to methods of use without limitation of "evoking a receptor potential in response to photostimulation in the optic nerve" and "an organic dye compound".

2) State of the prior art

The reference Nagano et al. JP 10134413 does not indicate which compounds of instant compounds may be useful in the claimed invention. Nagano et al. '413 is pertaining to Write-once optical disk having light-resistant and storage-stable organic dye layer.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to methods of use without limitation of "evoking a receptor potential in response to photostimulation in

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the optic nerve” and “an organic dye compound” by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to methods of use without limitation of “evoking a receptor potential in response to photostimulation in the optic nerve” and “an organic dye compound”, there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to methods of use without limitation of “evoking a receptor potential in response to photostimulation in the optic nerve” and “an organic dye compound”, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to methods of use without limitation of “evoking a receptor potential in response to photostimulation in the optic nerve” and “an organic dye compound”, however, the specification provides only limited examples of methods.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible “methods of use without limitation of “evoking a receptor potential in response to photostimulation in the optic nerve” and “an organic dye compound””.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous methods in order to obtain "methods of use without limitation of "evoking a receptor potential in response to photostimulation in the optic nerve" and "an organic dye compound"" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975.

Incorporation of the limitation "methods of use without limitation of "evoking a receptor potential in response to photostimulation in the optic nerve" and "an organic dye compound", i.e., diseases on page 15, lines 13-28, and compounds of formulae 14-17 on page 10.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

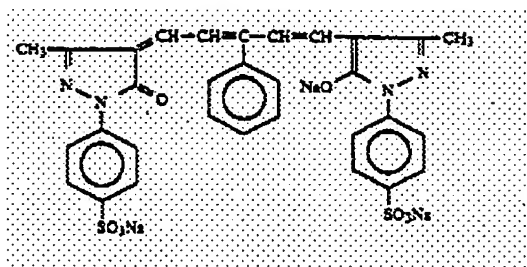
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by (1) Momose-Sato et al., publication, Journal of Membrane Biology, (1999), 172(2), 145-157, see CAS: 132:90253; or (2) Koshiishi et al. US 5,132,095.

Applicants claim a method of use using organic dye compounds (i.e., compounds of formula 14-17) to evoke a receptor in response to photostimulation.

Momose-Sato et al. disclose three compounds (1) Benzenesulfonic acid, 4-[4,5-dihydro-4-[5-[5-hydroxy-3-methyl-1-(4-sulfophenyl)-1H-pyrazol-4-yl]-3-phenyl-2,4-pentadienylidene]-3-methyl-5-oxo-1H-pyrazol-1-yl]- (i.e., NK3041 or RH155); (2) 1(4H)-Quinolinebutanesulfonic acid, 4-[4-(3-butyl-4-oxo-2-thioxo-5-thiazolidinylidene)-2-butenylidene]-, sodium salt (i.e., NK 2761); and (3) Benzenesulfonic acid, 4-[4,5-dihydro-4-[5-[5-hydroxy-3-methyl-1-(4-sulfophenyl)-1H-pyrazol-4-yl]-3-phenyl-2,4-pentadienylidene]-3-methyl-5-oxo-1H-pyrazol-1-yl]-, trisodium salt (i.e., NK3630), which clearly anticipate the instant compounds, i.e., formulae 14, 16, and 17, as dye agent for optical measurement of neural activity, see page 148, or see RN: 135806-37-0, 254729-07-2, and 79953-79-0 of DN:132:90253.

Koshiishi et al. disclose a compound of the formula,



, which clearly anticipate the instant compounds, i.e., formula 16 or its salt, as dye agent for optical sensor, see column 4, line 60-65, and column 7, lines 5-15.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

9. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Momose-Sato et al., publication, Journal of Membrane Biology, (1999), 172(2), 145-157, see CAS: 132:90253.

Applicants claim a method of use using organic dye compounds (i.e., compounds of formula 14-17) to evoke a receptor min response to photostimulation. The methods of use have been found on the pages 1-20 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

Momose-Sato et al. disclose three compounds (1) Benzenesulfonic acid, 4-[4,5-dihydro-4-[5-[5-hydroxy-3-methyl-1-(4-sulfophenyl)-1H-pyrazol-4-yl]-3-phenyl-2,4-pentadienylidene]-3-methyl-5-oxo-1H-pyrazol-1-yl]- (i.e., NK3041 or RH155); (2) 1(4H)-Quinolinebutanesulfonic acid, 4-[4-(3-butyl-4-oxo-2-thioxo-5-thiazolidinylidene)-2-butenylidene]-, sodium salt (i.e., NK 2761); and (3) Benzenesulfonic acid, 4-[4,5-dihydro-4-[5-[5-hydroxy-3-methyl-1-(4-sulfophenyl)-1H-pyrazol-4-yl]-3-phenyl-2,4-pentadienylidene]-3-methyl-5-oxo-1H-pyrazol-1-yl]-, trisodium salt (i.e., NK3630), which clearly anticipate the instant compounds, i.e., formulae 14, 16, and 17, as dye agent for

optical measurement of neural activity, see page 148, or see RN: 135806-37-0, 254729-07-2, and 79953-79-0 of DN:132:90253.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Momose-Sato et al. is that the instant claims silence the named compounds of organic dye compounds.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 7-12 prima facie obvious because one would be motivated to employ the compound of Momose-Sato et al. to obtain instant methods of use, wherein the organic dye compounds (i.e., compounds of formulae 14, 16-17 or their salts) are used for photostimulation in the optic nerve.

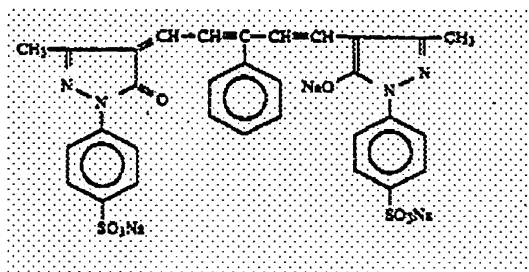
The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds would possess similar activities, i.e., photostimulation agents in the optic nerve, from the known Momose-Sato et al. compounds to that which is claimed in the reference.

10. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koshiishi et al. US 5,132,095.

Applicants claim a method of use using organic dye compounds (i.e., compounds of formula 14-17) to evoke a receptor min response to photostimulation. The methods of use have been found on the pages 1-20 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

Koshiishi et al. disclose a compound of the formula,



, as dye agent for optical sensor, see column 4, line 60-65, and column 7, lines 5-15.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Koshiishi et al. is that the instant claims silence the named compounds of organic dye compounds.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 7-12 prima facie obvious because one would be motivated to employ the compound of Koshiishi et al. to obtain instant methods of use, wherein the organic dye compounds (i.e., compounds of formulae 14-17 or their salts) are used for photostimulation in the optic nerve.

The motivation to make the claimed compounds derives from the expectation

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that the instant claimed compounds would possess similar activities, i.e., photostimulation agents in the optic nerve, from the known Koshiishi et al. compounds to that which is claimed in the reference.

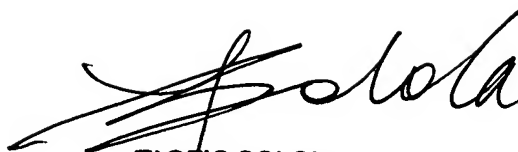
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish at the beginning.

TAOFIQ SOLOLA
PRIMARY EXAMINER

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

A handwritten signature in black ink, appearing to read 'R. Shiao', with a stylized flourish at the beginning.

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

June 28, 2005